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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/200,389

08/08/2005

Andrew Welcher

99-372-F1

3469

20306

7590

11/23/2007

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

11/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 11/200,389	<b>Applicant(s)</b> WELCHER ET AL.	
	<b>Examiner</b> Jegatheesan Seharaseyon, Ph.D	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-20 are present and examined.

#### ***Priority***

2. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/927, 850, filed 8/10/2001. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is

considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Specification***

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The use of the trademark Quick Spin(p.94) and Taq polymerase (p.102) etc. have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

### ***Drawings***

5. The drawing submitted on 8/8/2005 are acknowledged.

### ***Claim Rejections - 35 USC § 112, second paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6 and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claims 5, 6, 16, 17 and 18 recite the limitation "hybridization conditions" in the claims. The specification has failed to define the term so as to set forth the meets and bounds of the invention (The specification recites multiple hybridization conditions in pages 17-18). Further, the claims recite the percent mismatch allowable under the

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hybridization condition without providing the condition. Therefore, the metes and bounds of the claim are unclear. Claims 19 and 20 are rejected insofar as they are dependent on rejected claims 16, 17 or 18.

6b. Claims 16-18 are indefinite because the claims recite a process of producing a polypeptide comprising insertion of the polynucleotide of claims 16-18 into a host cell. Claims 16(d), 17(c) and 18(d) recite nucleotide sequences that are complementary to nucleotide sequences. It is not clear how the polynucleotide complements of claims 16(d), 17(c) and 18(d) will produce the polypeptide disclosed in the instant application, because the complement is not the coding strand. A complement is a sequence of nucleotide bases in one strand of a DNA or RNA molecule that is exactly complementary (adenine-thymine, adenine-uracil, or guanine-cytosine) to that on another single strand. Claims 19 and 20 are rejected insofar as they are dependent on rejected claims 16, 17 or 18.

6c. Claims 2, 5 and 17 are rejected as being vague and indefinite in the recitation of the term "at least about". While at least provides a lower limit, at least about is indefinite. The specification nor the prior art provide any indication as to what range is covered by the term "about". Claims 7, 8, 9, 11, 12, 13, 14, 15, 19 and 20 are rejected insofar as they are dependent on rejected claims 2 and 17.

### ***Claim Rejections - 35 USC § 112, first paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptide of SEQ ID NO: 5 or SEQ ID NO: 6 or polypeptide encoded by nucleic acids of SEQ ID NO: 4 or the polypeptide encoded by the insert in ATCC Deposit No. PTA-976, does not reasonably provide enablement for all possible variants including those that are at least 70% identical to SEQ ID NO: 5 or fragments of SEQ ID NO: 5 or the polypeptide encoded by the nucleotide which hybridizes with no more than 21% mismatch (sequence identified hybridization) or complementary sequences contemplated by the Applicant. The claims also recite the phrases “an amino acid sequence” and “a nucleic acid molecule” and thus, are broadly interpreted by the Examiner as reading upon: (i) DNA and protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NOs: 4-6, including sequences only 25 amino acids or 75 nucleic acids in length (see specification page 16). The claims also read on multiple polypeptides encoded DNA inserts in ATCC No. PTA-976. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention as claimed.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”

include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims reads on amino acid sequence variants including those that are at least 70% identical to SEQ ID NO: 5 or fragments of SEQ ID NO: 5 or the polypeptide encoded by the nucleotide which hybridizes with no more than 21% mismatch (sequence identified hybridization) or complementary sequences contemplated by the Applicant. The claims also recite the phrases “an amino acid sequence” and “a nucleic acid molecule” and thus, are broadly interpreted by the Examiner as reading upon: (i) DNA and protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NOs: 4-6, including sequences only 25 amino acids or 75 nucleic acids in length (see specification page 16). The claims also read on multiple polypeptides encoded DNA inserts in ATCC No. PTA-976. However, other than the nucleic acid sequence of SEQ ID NO: 4 and polypeptide of SEQ ID NO: 5 and 6, the specification as filed fails to disclose any other polypeptide or nucleic acid sequences recited in the instant claim. The specification does not teach functional or structural characteristics of the polypeptide variants, fragments, and derivatives encompassed by the claims.

Despite knowledge in the art for producing variant polynucleotide that encode polypeptides, the specification fails to provide any guidance regarding the variant



polynucleotide sequences encoding the polypeptides by the contemplated methods that retain the function. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, *Biochemistry* 29:8509-8517; Ngo et al., 1994, *The Protein Folding Problem and Tertiary Structure Prediction*, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized

procedures for producing and screening for active variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. Therefore, predicting which polypeptide, if any, would retain the functions of the protein is well outside the realm of routine experimentation. Further, since no function has been attributed to the claimed protein, the skilled artisan would not know what function to test for. Thus, an undue amount of experimentation would be required to generate the changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicant has not taught how one of skill in the art would use the full scope of polypeptide sequences encompassed by the invention of claims 1-20. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences.

Given the breadth of claims 1-20 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior art of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification,

it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

7b. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses the polypeptide of SEQ ID NO: 5 or SEQ ID NO: 6 or polypeptide encoded by nucleic acids of SEQ ID NO: 4 or the polypeptide encoded by the insert in ATCC Deposit No. PTA-976. This meets the written description provisions of 35 USC 112, first paragraph. However, the specification does not disclose all possible variants all possible variants including those that are at least 70% identical to SEQ ID NO: 5 or fragments of SEQ ID NO: 5 or the polypeptide encoded by the nucleotide which hybridizes with no more than 21% mismatch (sequence identified hybridization) or complementary sequences contemplated by the Applicant. The claims also recite the phrases "an amino acid sequence" and "a nucleic acid molecule" and thus, are broadly interpreted by the Examiner as reading upon: (i) DNA and protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NOs: 4-6, including sequences only 25 amino acids or 75 nucleic acids in length (see specification page 16). The claims also read on multiple polypeptides encoded DNA inserts in ATCC No. PTA-976. The claims as written, however,

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encompass variant sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 1-20. The specification does not provide written description to support the genus encompassed by the instant claims.

*Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

With the exception of isolated polypeptide of SEQ ID NO: 5 or SEQ ID NO: 6 or polypeptide encoded by nucleic acids of SEQ ID NO: 4 or the polypeptide encoded by the insert in ATCC Deposit No. PTA-976, the skilled artisan cannot envision all the detailed chemical structure of the claimed polypeptide sequences of the variants and fragments regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class.

Therefore, only the isolated polypeptide of SEQ ID NO: 5 or SEQ ID NO: 6 or polypeptide encoded by nucleic acids of SEQ ID NO: 4 or the polypeptide encoded by the insert in ATCC Deposit No. PTA-976, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically

disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various polynucleotide sequences set forth in claims 1-20.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

7c. Claims 1-20 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such away as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants' referral to the deposit of PTA-976 in the specification and in claims 1, 4, 5, 16 and 17 are insufficient assurance that all of the conditions of 37CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is

necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8a. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by La Fleur et al. (U. S. Patent No. 6, 433, 145, priority date of July 21, 1998).

Claims are drawn to isolated amino acid sequences. The claims also recite the phrases “an amino acid sequence” and “ a nucleic acid molecule” and thus, are broadly interpreted by the Examiner as reading upon: (i) DNA and protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NOs: 4-6, including sequences only 25 amino acids or 75 nucleic acids in length (see specification page 16).

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The La Fleur et al. reference teaches SEQ ID NO: 2, which is identical to the instant SEQ ID NO: 5 (see below search results).

```
RESULT 1
US-09-487-792-2
; Sequence 2, Application US/09487792
; Patent No. 6433145
; GENERAL INFORMATION:
; APPLICANT: Human Genome Sciences, Inc.
; TITLE OF INVENTION: Keratinocyte Derived Interferon
; FILE REFERENCE: PF482P1
; CURRENT APPLICATION NUMBER: US/09/487,792
; CURRENT FILING DATE: 2000-01-20
; EARLIER APPLICATION NUMBER: 60/093,643
; EARLIER FILING DATE: 1998-07-21
; EARLIER APPLICATION NUMBER: PCT/US99/16424
; EARLIER FILING DATE: 1999-07-21
; NUMBER OF SEQ ID NOS: 54
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 2
;   LENGTH: 207
;   TYPE: PRT
;   ORGANISM: Homo sapiens
US-09-487-792-2
```

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Query Match          100.0%;   Score 1101;   DB 2;   Length 207;
Best Local Similarity 100.0%;   Pred. No. 2e-109;
Matches 207;   Conservative    0;   Mismatches    0;   Indels    0;   Gaps
0;
```

```
Qy      1 MSTKPDMIQKCLWLEILMGIFIAGTSLSDCNLLNVHLRRVTWQNLRLHSSMSNSFPVECL 60
        |
Db      1 MSTKPDMIQKCLWLEILMGIFIAGTSLSDCNLLNVHLRRVTWQNLRLHSSMSNSFPVECL 60

Qy     61 RENIAFELPQEFLOYTQPMKRDIKKAFYEMSLQAFNIFSQHTFKYWKERHLKQIQIGLDQ 120
        |
Db     61 RENIAFELPQEFLOYTQPMKRDIKKAFYEMSLQAFNIFSQHTFKYWKERHLKQIQIGLDQ 120

Qy    121 QAEYLNQCLEEDENENEDMKEMKENEMKPSEARVPQLSSLELRRYFHRIDNFLKEKKYSD 180
        |
Db    121 QAEYLNQCLEEDENENEDMKEMKENEMKPSEARVPQLSSLELRRYFHRIDNFLKEKKYSD 180

Qy    181 CAWEIVRVEIRRCLYYFYKFTALFRRK 207
        |
Db    181 CAWEIVRVEIRRCLYYFYKFTALFRRK 207
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Variants are taught in column 20, lines 39-45. Fragments are taught in column 14, lines 48-63 and columns 35-37. Pharmaceutically acceptable carriers are taught in

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column 80, lines 1-38. SEQ ID NO: 6, claimed in claim 10, is residues 30-207 of SEQ ID NO: 2 disclosed in '145 patent. This fragment is taught in column 14, line 57.

Derivatives. Including polymers, are taught in column 10, lines 2-41. Fusion proteins are taught in column 56, lines 38-46. Expression in eukaryotic and prokaryotic cells is taught in column 86, lines 14-26. Thus, the '145 patent teaches each of the limitations of instant claims 1-20. Therefore, claims 1-20 are rejected as being anticipated by La Fleur et al. (U. S. Patent No. 6, 433, 145).

### ***Conclusion***

9. No Claims are allowable.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSS

November 16, 2007

/Jegatheesan Seharaseyon, Ph.D/  
Examiner, Art Unit 1647